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Established in 1953

February 11, 2020

Honorable Freda L. Wolfson, Chief Judge
United States District Court
Clarkson S. Fisher Building & US Courthouse
402 East State Street
Trenton, NJ 08608

Re: *In Re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Products Liability Litigation* (MDL No. 2738)

Dear Chief Judge Wolfson:

The Plaintiffs' Steering Committee writes to provide the Court with additional scientific materials that support the PSC's general causation experts' opinions that Johnson & Johnson's talcum powder products can cause ovarian cancer.

The International Agency for the Research on Cancer (IARC) recently published the "Report of the Advisory Group to Recommend Priorities for the *IARC Monographs* during 2020-2024," attached as Exhibit A. IARC classified talc *without* asbestiform fibers as a possible carcinogen (Group 2B) in 2010. The Working Group, having reviewed studies published since this initial review was completed in 2006, has made it a high priority to re-evaluate domestic talc products, i.e., talc-based body powders. *See* Ex. A at 73. In support of their recommendation, the Working Group cited the Penninkilampi (2018) study, which was relied upon by the PSC's experts and which summarizes new studies, including prospective cohort studies, reporting a "modestly elevated but precise overall odds ratio of 1.31 (95% confidence interval [CI], 1.24-1.39)." *Id.* at 72. They noted that there was a slight gradient in risk or dose response with increased exposure. *Id.* IARC also noted that mechanistic evidence has been updated since 2006:

There is evidence to suggest that when talc is used in the genital area, talc enters the vagina and migrates to the upper genital tract (Cramer et

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al., 2007), where it may induce inflammatory reactions capable of damaging genital tissue DNA. Serous subtypes originate in the fallopian tube; this may enhance the plausibility of the observed associations in epidemiological studies. An in vitro study of epithelial ovarian and normal cells found that both were stimulated by talc to exhibit oxidative stress (Fletcher et al., 2019 [Saed]). Ovarian toxicity in rats was also observed after talc exposure (Yumrutas et al., 2015), and the pilot study of Sprague-Dawley rats noted above found inflammatory changes in the reproductive system, including increased numbers of follicles (Keskin et al., 2009).

Id. at 73. These studies and the purposes for which IARC cites them support the opinions of the PSC's experts.

In addition, the U.S. Food and Drug Administration (FDA) has formed an Interagency Working Group on Asbestos in Consumer Products (IWGACP). The working group is composed of representatives from the FDA, National Institutes for Occupational Safety and Health (NIOSH), National Institute of Health (NIH)/ National Institute of Environmental Health Sciences (NIEHS), Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), the National Institute of Standards & Technology (NIST), and the Department of Interior's U.S. Geological Survey (USGS).

On January 6, 2020, the IWGACP issued preliminary recommendations on testing methods for asbestos in talc and consumer products containing talc. *See* Exhibit B. The IWGACP "strongly recommended the use of TEM with energy dispersive X-ray spectroscopy (EDS) and selected area electron diffraction (SAED) analyses to reliably detect and identify chrysotile and asbestiform and non-asbestiform amphibole minerals." *Id.* at 5 (¶5). They recommended that "testing laboratories report all EMPs having length $\geq 0.5 \mu$." *Id.* (¶ 2). They recommended that individual fibers be reported instead of a "mass percent, a unit that is frequently used to express content of asbestos in commercial bulk materials." *Id.* (¶4, 6).

The IWGACP's recommended methodology for testing talc for asbestiform minerals (asbestos and fibrous talc) are entirely consistent with and supportive of the methodology that Drs. Longo and Rigler used when testing Johnson & Johnson's historical samples. As recently as February 4, 2020, the FDA held a public hearing

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to solicit public comment on the IWGACP's testing recommendations. Scientists and medical experts with experience in numerous disciplines including a few PSC experts participated along with interested persons in the all-day meeting. The PSC will provide to the Court relevant statements, power point presentations and official hearing transcripts when all are made available.

Lastly, in its December 24, 2019 submission to the Court, the PSC brought to the Court's attention the recent scientific publication, Steffen, JE., et al. *Serous Ovarian Cancer Caused by Exposure to Asbestos in Cosmetic Talc Powders – A Case Series Serous Ovarian Cancer Caused by Asbestos in Cosmetic Talc*. Journal of Occupational and Environmental Medicine. DOI: 10.1097/JOM.0000000000001800. (published ahead of print) (Dec. 23, 2019). At that time, the only version available was a pre-publication galley proof. The PSC now attaches for the record a published version of the manuscript. *See* Exhibit C.

We thank the Court for its consideration of these additional scientific publications.

Respectfully submitted,

/s/ Michelle A. Parfitt
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/s/ P. Leigh O'Dell
P. Leigh O'Dell

cc: All counsel of record via ECF notification